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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/021,509	12/07/2001	Marie-Claude Gingras	HO P02046US1	8559

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EXAMINER	
BELYAVSKYI, MICHAIL A	
ART UNIT	**PAPER NUMBER**
1644	

DATE MAILED: 10/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/021,509	GINGRAS ET AL.	
	Examiner	Art Unit	
	Michail A. Belyavskyi	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 September 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3,5,11,15,16 and 39-42* is/are pending in the application.

4a) Of the above claim(s) *39 and 42* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 3, 5, 11, 15, 16, 40 and 41* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's amendment, filed 09/12/05 is acknowledged.

2. Claims 1, 3, 5, 11, 15, 16, 39-42 are pending.

3. Newly submitted claim 39 and 42 directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: The invention of the Elected Group I, now claims 1, 3, 5, 11, 15, 16, 40 and 41 are drawn to a method of modulating an immune response, comprising the step of administering a soluble polypeptide variant of TREM-1. The invention of newly submitted claim 39 is drawn to a method of modulating an immune response comprising administering composition comprising an antisense RNA. These invention are different with respect to ingredients and method steps which require non-coextensive searches, therefore each method is patentably distinct.

4. Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits.

Accordingly, claims 39 and 42 withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claims 1, 3, 5, 11, 15, 16, 40 and 41 drawn to a method of decreasing an immune response, a method of decreasing myeloid cell activation and a method of decreasing an inflammatory response each comprising the step of administering a soluble polypeptide variant of TREM-1 are under consideration in the instant application.

In view of the amendment, filed 09/12/05 the following rejections remain:

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> *The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.*

6. Claims 1, 3, 5, 11, 15, 16, 40 and 41 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make

and/or use the invention for the same reasons set forth in the previous Office Action, mailed 03/11/05.

Applicant's arguments, filed 09/12/05 have been fully considered, but have not been found convincing.

Applicant asserts that : (i) the mechanism by which the polypeptide competes for the TREM-1 ligand is described throughout the specification, (ii) although the specification does not teach how to make every soluble variant of TREM-1, the disclose functional equivalent and soluble variants would be attained by conventional and routinely practiced molecular biology techniques used by those in the art; (iii) the structure of different TREM-1 molecules across species have been studied and their ligand binding site is a common conservative region, as supported by Kelker et al., (iv) One can practice the claimed invention because one can predict the therapeutical efficacy of the composition with TREM-1 ligand activity; (iv) Bouchon et al (Nature ,2001, 410 1103-1107) reference utilized the teaching of the present invention, thus showing the enablement of the present invention.

Contrary to Applicant's assertion, the issue raised in the previous Office Action was not about the proposed mechanism of action of soluble polypeptide variant of TREM. As was stated in the previous Office Action, the specification only discloses: (i) the levels of TREM-1 expression in various tissues and cell types (see Examples 4 and 5 in particular); (ii) the levels of TREM-1 splice variant, in samples collected from normal individuals and individual suffering from an autoimmune disease (see example 10 in particular); (iii) *in vitro* data indicating that TREM-1 splice variant, a polypeptide comprising SEQ ID NO:2 can down regulate LPS-induced cytokine production (see example 11 in particular); (iv) a competitive inhibitor for the ligand of TREM-1, wherein said competitive inhibitor is a polypeptide comprising SEQ ID NO:2 (see page 14 in particular). The specification does not adequately teach how : (i) effectively modulate *any* immune response by administering an effective amount of composition comprising *any* soluble polypeptide comprising at least a portion of amino acid 1 to 136 of SEQ ID NO:2 or any polypeptide mimetic thereof in the amount effective to modulate the levels of TREM-1 and or TREM-1SV ligan binding activity, claimed in claim 1 or (ii) effectively modulate *any* immune response by administering an effective amount of composition comprising *any* soluble polypeptide comprising at least a portion of amino acid 36 to 114 of SEQ ID NO:2 the whole portion of amino acid 36-114 of SEQ ID NO:2 or more than the whole portion of amino acids 36-114 of SEQ ID NO:2, claimed in claim 2. Moreover, no animals models were used to study the effectively to (i) effectively modulate *any* immune response by administering an effective amount of composition comprising *any* soluble polypeptide comprising at least a portion of amino acid 1 to 136 of SEQ ID NO:2 or any polypeptide mimetic thereof in the amount effective to modulate the levels of TREM-1 and or TREM-1SV ligan binding activity, claimed in claim 1 or (ii) effectively modulate *any* immune response by administering an effective amount of composition comprising *any* soluble polypeptide comprising at least a portion of amino acid 36 to 114 of SEQ ID NO:2 the whole portion of amino acid 36-114 of SEQ ID NO:2 or more than the whole portion of amino acids 36-114 of SEQ ID NO:2, claimed

in claim 2. The specification only states that it is envisioned that administering of TREM-1 splice variant may resulting down regulation of the inflammatory response (see page 45 in particular). Similarly, the Declaration under 37 CFR 1.132 by Dr. Gingras only stated that the inventors **envisioned** modulating inflammation in septic shock by administering a competitive inhibitor of the ligand for TREM-1 (see page 1 in particular). Moreover, the Examiner does not find a support in said declaration for the asserted statement that "Declaration under 37 CFR 1.132 by Dr. Gingras disclosed that the teaching of the present invention show that a soluble TREM-1 inhibits cell function **in a mouse model**". Dr. Gingras only stated that should the prophetic examples disclosed in the instant application be performed, the obtained results might be similar to those of Bouchon et al. However, it is noted that said the prophetic experiments have not actually been performed. In addition, Bouchon et al., (Nature ,2001, 410 1103-1107) reference only teaches a very specific mTREM-1/IgG1 fusion protein, not *any* compound that was used in experimental endotoxic shock on murine models. However, Bouchon et al., explicitly stressed that experimental endotoxic shock reproduced human sepsis only in part as it does not involve the replication and dissemination of bacteria (see page 1105 in particular). The is no teaching or suggestion in Bouchon et al. to: (i) effectively modulate *any* immune response by administering an effective amount of composition comprising *any* soluble polypeptide comprising at least a portion of amino acid 1 to 136 of SEQ ID NO:2 or any polypeptide mimetic thereof in the amount effective to modulate the levels of TREM-1 and or TREM-1SV ligan binding activity, claimed in claim 1 or (ii) effectively modulate *any* immune response by administering an effective amount of composition comprising *any* soluble polypeptide comprising at least a portion of amino acid 36 to 114 of SEQ ID NO:2 the whole portion of amino acid 36-114 of SEQ ID NO:2 or more than the whole portion of amino acids 36-114 of SEQ ID NO:2, claimed in claim 2.

With regasrds to Applicant's comments that the structure of different TREM-1 molecules across species have been studied and their ligand binding site is a common conservative region, as supported by Kelker et al. It is noted that Kelker et al., explicitly stated that " the structural data presented here do not unfortunately allow for very informed speculation on precise ligand binding sites or on potential ligand (see page 1180 in particular).

Since there is no animal model studies and data in the specification to show the effectively of effectively modulate *any* immune response by administering an effective amount of composition comprising *any* soluble polypeptide comprising at least a portion of amino acid 1 to 136 of SEQ ID NO:2 or any polypeptide mimetic thereof in the amount effective to modulate the levels of TREM-1 and or TREM-1SV ligand binding activity, claimed in claim 1 or (ii) effectively modulate *any* immune response by administering an effective amount of composition comprising *any* soluble polypeptide comprising at least a portion of amino acid 36 to 114 of SEQ ID NO:2 the whole portion of amino acid 36-114 of SEQ ID NO:2 or more than the whole portion of amino acids 36-114 of SEQ ID NO:2, claimed in claim 2 it is unpredictable how to correlate *in vitro* results with *in vivo* use. Therefore, it is the Examiner position that it is not clear that the skilled artisan could predict the efficacy of a method of effectively modulate *any* immune response by administering an effective amount of composition comprising *any* soluble polypeptide comprising at least a portion of amino acid 1 to 136 of SEQ

ID NO:2 or any polypeptide mimetic thereof in the amount effective to modulate the levels of TREM-1 and or TREM-1SV ligan binding activity, claimed in claim 1 or (ii) effectively modulate *any* immune response by administering an effective amount of composition comprising *any* soluble polypeptide comprising at least a portion of amino acid 36 to 114 of SEQ ID NO:2 the whole portion of amino acid 36-114 of SEQ ID NO:2 or more than the whole portion of amino acids 36-114 of SEQ ID NO:2, claimed in claim 2. Thus in the absence of working examples or detailed guidance in the specification, the intended *in vivo* uses of composition comprising *any* soluble polypeptide comprising at least a portion of amino acid 1 to 136 of SEQ ID NO:2 or any polypeptide mimetic thereof or composition comprising *any* soluble polypeptide comprising at least a portion of amino acid 36 to 114 of SEQ ID NO:2 the whole portion of amino acid 36-114 of SEQ ID NO:2 or more than the whole portion of amino acids 36-114 of SEQ ID NO:2 to modulate any immune response are fraught with uncertainties.

Also an issue that applicant has not taught how to make and/or use *any* soluble polypeptide comprising at least a portion of amino acid 1 to 136 of SEQ ID NO:2 or any polypeptide mimetic thereof or composition comprising *any* soluble polypeptide comprising at least a portion of amino acid 36 to 114 of SEQ ID NO:2, the whole portion of amino acid 36-114 of SEQ ID NO:2 or more than the whole portion of amino acids 36-114 of SEQ ID NO:2 to effectively modulate an immune.

"Comprising" is considered open-ended claim language and includes amino acid residues outside of the specified peptide. Therefore, a peptide comprising at least a portion of amino acid 1 to 136 of SEQ ID NO:2 or any polypeptide mimetic thereof or composition comprising *any* soluble polypeptide comprising at least a portion of amino acid 36 to 114 of SEQ ID NO:2 the whole portion of amino acid 36-114 of SEQ ID NO:2 or more than the whole portion of amino acids 36-114 of SEQ ID NO:2 includes an unlimited number of amino acid sequences "comprising" an unlimited number of polypeptides. The disclosure of SEQ ID NOs: 2 and 28 cannot support the entire genus of peptides comprising at least a portion of amino acid 1 to 136 of SEQ ID NO:2 or any polypeptide mimetic thereof or composition comprising *any* soluble polypeptide comprising at least a portion of amino acid 36 to 114 of SEQ ID NO:2 the whole portion of amino acid 36-114 of SEQ ID NO:2 or more than the whole portion of amino acids 36-114 of SEQ ID NO:2 as part of their sequence that can be used to modulate an immune response.

Applicant is relying upon certain biological activities and the disclosure of a single species to support an entire genus. It is well known that minor structural differences among even structurally related compounds or compositions can result in substantially different biology, expression, and pharmacology of proteins. Therefore, structurally unrelated polypeptide "comprising at least a portion of amino acid 1 to 136 of SEQ ID NO:2 or any polypeptide mimetic thereof or composition comprising *any* soluble polypeptide comprising at least a portion of amino acid 36 to 114 of SEQ ID NO:2, the whole portion of amino acid 36-114 of SEQ ID NO:2 or more than the whole portion of amino acids 36-114 of SEQ ID NO:2" would be expected to have greater differences in their activities.

Thus, Applicant has not provided sufficient guidance to enable one skill in the art to use claimed (i) effectively modulate *any* immune response by administering an effective amount of composition comprising *any* soluble polypeptide comprising at least a portion of amino acid 1 to 136 of SEQ ID NO:2 or any polypeptide mimetic thereof in the amount effective to modulate the levels of TREM-1 and or TREM-1SV ligan binding activity, claimed in claim 1 or (ii) effectively modulate *any* immune response by administering an effective amount of composition comprising *any* soluble polypeptide comprising at least a portion of amino acid 36 to 114 of SEQ ID NO:2 the whole portion of amino acid 36-114 of SEQ ID NO:2 or more than the whole portion of amino acids 36-114 of SEQ ID NO:2, claimed in claim 2. in a manner reasonably correlated with the scope of the claims. The scope of the claims must bear a reasonable correlation with the scope of enablement. *In re Fisher*, 166 USPQ 18(CCPA 1970) indicates that the more unpredictable an area is, the more specific enablement is necessary in order to satisfy the statute.

In view of the quantity of experimentation necessary, the unpredictability of the art, the lack of sufficient guidance in the specification, the limited working examples, and the limited amount of direction provided given the breadth of the claims, it would take undue trials and errors to practice the claimed invention.

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:
A person shall be entitled to a patent unless --

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 37(c) of this title before the invention thereof by the applicant for patent.

8. Claims 1, 3, 5, 11, 15, 16, 40 and 41 are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent 6,420,526 or US Patent 6,504,010 forth in the previous Office Action, mailed 03/11/05.

Applicant's arguments, filed 09/12/05 have been fully considered, but have not been found convincing.

Applicant asserts that : (i)amended claim 1 is concerned with the new use of modulating immune response; (ii) none of the cited art teaches or suggests such specific intend, that is none of the prior art states that the composition, including a portion of SEQ ID NO:2 should be used to modulate the levels of TREM-1 and or TREM-1SV ligand binding.

Contrary to Applicant's assertion, it is noted that it is the Examiner position that all prior art teaches the use of referenced polypeptides to modulate immune response.
As has been stated previously, applicant relies upon an asserted and claimed mechanism of action but does not provide objective evidence that the prior art teaching of administering of polypeptide that is identical to the claimed polypeptide comprising SEQ ID NO:2 to achieve the same therapeutic effect differs from the claimed methods.

The sequence alignment, shown that polypeptide comprising SEQ ID NO:2 of the instant application is 100 % identical to SEQ ID NO: 478 of US Patent '526 or 100 % identical to SEQ ID NO: 1825 of US Patent '010. It is noted that the term "comprises" is open-ended term. It means that a peptide may include additional unrecited amino acids on either or both of the N- or C- termini of given sequence and thus can read on the recited polypeptide. Moreover, US Patent'526 teaches that polypeptides of the invention comprises the extracellular domain alone or fused to the intracellular domain i.e. lacking the transmembrane domain, i.e soluble polypeptide (see column 145, lines 1-10 in particular). Similarly, US Patent ' 010 teaches that in certain embodiments the peptides of the invention may include peptides in which an N-terminal leader sequense and/or transmembrane domain have been deleted (see column 45, lines 55-65 in particular).

As was stated in the previous Office Action, it is the Examiner position that US Patent '526 teaches a method of modulating an immune responses, i.e. decreasing an inflammatory response in a subject suffering from disease comprising administering a polypeptide of SEQ ID NO: 478 in a pharmaceutical carrier (see entire document , abstract, columns 4, 8 ,77 in particular). US Patent '526 teaches that disease are infectious disease, GVHD and septic shock (see column 77 and 132 in particular). Although the reference is silent about decreasing the activity of DAP12/TREM1 complex after administering of SEQ ID NO: 478, or that SEQ ID NO: 478 is a competitive inhibitor of the ligand to TREM-1 these functional limitations would be inherent properties of said polypeptide because it is 100 % identical with the claimed polypeptide comprising SEQ ID NO:2. Since the office does not have a laboratory to test the reference polypeptide, it is applicant's burden to show that the reference polypeptide does not decrease the activity of DAP12/TREM1 complex or not a competitive inhibitor of the ligand to TREM-1 as recited in the claims. See *In re Best*, 195 USPQ 430, 433 (CCPA 1977); *In re Marosi*, 218 USPQ 289, 292-293 (Fed. Cir. 1983); *In re Fitzgerald et al.*, 205 USPQ 594 (CCPA 1980).

Claims 11, 15, 16 and 40-41 are included because the claimed functional limitation would be inherent properties of the a method of modulation an immune response and a method of modulation an inflammatory response in a subject suffering from disease comprising administering a polypeptide of SEQ ID NO: 478 taught by US Patent '526 because the referenced polypeptide of SEQ ID : 478 used in the referenced methods is 100 % identical with the claimed polypeptide comprising SEQ ID NO:2 used in the claimed methods. It is clear that US Patent '526 and the current application administered the same compound to

achieved the same results in the same patients thus the reference polypeptide would inherently performed the intended use. If the prior art structure is capable of performing the intended use, then it meets the claim. When a claim recites using an old composition or structure (e.g. polypeptide of SEQ ID NO: 478) and the use is directed to a result or property of that composition or structure then the claim is anticipated. In addition, under the principles of inherency, if a prior art method, in its normal and usual operation, would necessarily perform the method claimed, then the method claimed will be considered to be anticipated by the prior art. When the prior art method is the same as a method described in the specification, it can be assumed the method will inherently perform the claimed process. See MPEP 2112.02 . Also, see Bristol-Myers Squibb Co. v. Ben Venue Laboratories, Inc. 58 USPQ2d 1508 (CA FC 2001); Ex parte Novitski 26 USPQ 1389 (BPAI 1993); Mehl/Biophile International Corp. V. Milgraum, 52 USPQ2d 1303 (Fed. Cir. 1999); Atlas Powder Co. V. IRECO, 51 USPQ2d 1943 (Fed. Cir. 1999).

Similarly, US Patent '010 teaches a method of therapy of an immune response in a subject suffering from disease comprising administering a polypeptide of SEQ ID NO: 1825 in a pharmaceutical carrier (see entire document , abstract, column 3, 45, 46, 78 and 79 in particular). It is noted that polypeptide compising SEQ ID :2 an of the instant application is 100 % identical to SEQ ID NO: 1825 of US Patent '010 (see attached sequence alignment). Although the reference is silent about decreasing the activity of DAP12/TREM1 complex after administering of SEQ ID NO: 1825, or that SEQ ID NO: 1825 is a competitive inhibitor of the ligand to TREM-1 these functional limitations would be inherent properties of said polypeptide because it is 100 % identical with the claimed SEQ ID NO:2. Since the office does not have a laboratory to test the reference polypeptide, it is applicant's burden to show that the reference polypeptide does not decrease the activity of DAP12/TREM1 complex or not a competitive inhibitor of the ligand to TREM-1 as recited in the claims. See *In re Best*, 195 USPQ 430, 433 (CCPA 1977); *In re Marosi*, 218 USPQ 289, 292-293 (Fed. Cir. 1983); *In re Fitzgerald et al.*, 205 USPQ 594 (CCPA 1980).

Claims 11, 15, 16 and 40-41 are included because the claimed functional limitation would be inherent properties of the a method of modulation an immune response and a method of modulation an inflammatory response in a subject suffering from disease comprising administering a polypeptide of SEQ ID NO: 1825 taught by US Patent '010 because the referenced polypeptide of SEQ ID : 010 used in the referenced methods is 100 % identical with the claimed SEQ ID NO:2 used in the claimed methods. It is clear that US Patent '010 and the current application administered the same compound to achieved the same results in the same patients thus the reference polypeptide would inherently performed the intended use. If the prior art structure is capable of performing the intended use, then it meets the claim. When a claim recites using an old composition or structure (e.g. polypeptide of SEQ ID NO: 1825) and the use is directed to a result or property of that composition or structure then the claim is anticipated. In addition, under the principles of inherency, if a prior art method, in its normal and usual operation, would necessarily perform the method claimed, then the method claimed will be considered to be anticipated by the prior art. When the prior art method is the same as a method described in the specification, it can be assumed the method will inherently perform the

claimed process. See MPEP 2112.02 . Also, see Bristol-Myers Squibb Co. v. Ben Venue Laboratories, Inc. 58 USPQ2d 1508 (CA FC 2001); Ex parte Novitski 26 USPQ 1389 (BPAI 1993); Mehl/Biophile International Corp. V. Milgraum, 52 USPQ2d 1303 (Fed. Cir. 1999); Atlas Powder Co. V. IRECO, 51 USPQ2d 1943 (Fed. Cir. 1999).
As pointed out previously, the mechanism of action does not have a bearing on the patentability of the invention if the invention was already known or obvious. Even though applicant has proposed or claimed the mechanism by which a particular compound decrease myeloid cell activation it does not appear to distinguish the prior art teaching the same or nearly the same methods to achieve the same endresult. Mere recognition of latent properties in the prior art does not render nonobvious an otherwise known invention. In re Wiseman, 201 USPQ 658 (CCPA 1979). Granting a patent on the discovery of an unknown but inherent function would remove from the public that which is in the public domain by virtue of its inclusion in, or obviousness from, the prior art. In re Baxter Travenol Labs, 21 USPQ2d 1281 (Fed. Cir. 1991). See M.P.E.P. 2145.

The reference teaching anticipates the claimed invention.

The following new grounds of rejection is necessitated by the amendment, filed on 09/12/05

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:
The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claims 1, 3, 5, 11, 15, 16, 40 and 41 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This is a New Matter rejection**.

" composition comprising at least a portion of amino acid 1 to 136 of SEQ ID NO:2 or any polypeptide mimetic thereof in the amount effective to modulate the levels of TREM-1 and or TREM-1SV ligand binding activity", claimed in claim 1 or (ii) " composition comprising *any* soluble polypeptide comprising at least a portion of amino acid 36 to 114 of SEQ ID NO:2 the whole portion of amino acid 36-114 of SEQ ID NO:2 or more than the whole portion of amino acids 36-114 of SEQ ID NO:2", claimed in claim 2, " wherein composition comprising at least a portion of amino acid 1 to 136 of SEQ ID NO:2 or any polypeptide mimetic thereof modulates

LPS-induced cytokine production", claimed in claim 41 represent a departure from the specification and the claims as originally filed. The passages pointed by the applicant do not provide a clear support for " composition comprising at least a portion of amino acid 1 to 136 of SEQ ID NO:2 or any polypeptide mimetic thereof in the amount effective to modulate the levels of TREM-1 and or TREM-1SV ligand binding activity", claimed in claim 1 or (ii) " composition comprising *any* soluble polypeptide comprising at least a portion of amino acid 36 to 114 of SEQ ID NO:2 the whole portion of amino acid 36-114 of SEQ ID NO:2 or more than the whole portion of amino acids 36-114 of SEQ ID NO:2", claimed in claim 2, " wherein composition comprising at least a portion of amino acid 1 to 136 of SEQ ID NO:2 or any polypeptide mimetic thereof modulates LPS-induced cytokine production", claimed in claim 41 The specification and the claims as originally field only support " variant of TREM-1".

11. No claim is allowed

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michail Belyavskyi whose telephone number is 571/ 272-0840 The examiner can normally be reached Monday through Friday from 9:00 AM to 5:30 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571/ 272-0841 .

The fax number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Michail Belyavskyi, Ph.D.
Patent Examiner
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October 14, 2005

Christina Chan

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